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19
20 UNITED STATES DISTRICT COURT
21
22 NORTHERN DISTRICT OF CALIFORNIA

23
24 IN RE RIGEL PHARMACEUTICALS, INC.
25 SECURITIES LITIGATION.

26 Master File No. CV 09-0546 JSW

27 CLASS ACTION

28 **RIGEL AND INDIVIDUAL DEFENDANTS'
NOTICE OF MOTION AND MOTION TO
DISMISS CONSOLIDATED AMENDED
COMPLAINT; MEMORANDUM OF POINTS
AND AUTHORITIES**

Date: April 9, 2010
Time: 9:00 a.m.
Courtroom: 11, 19th floor
Judge: Hon. Jeffrey S. White

29
30 This Document Relates To: All Actions

Table of Contents

2	I.	INTRODUCTION AND SUMMARY OF ARGUMENT	2
3	II.	STATEMENT OF ALLEGATIONS AND FACTS SUBJECT TO JUDICIAL	
4		NOTICE	3
5	A.	The Parties.....	3
6	B.	Rheumatoid Arthritis, R788 and the Phase IIa Clinical Trial	3
7	C.	December 2007: Initial Reports of the Results of the Phase IIa Trial	4
8	D.	February 2008: Rigel's Secondary Offering	5
9	E.	October-November 2008: Clinical Presentation of Trial Results	5
10	F.	Rigel's Statements Regarding Potential Partnering Opportunities	7
11	III.	LEGAL STANDARDS.....	8
12	IV.	THE CAC SHOULD BE DISMISSED AS PLAINTIFF FAILED TO FOLLOW	
13		THE COURT'S ORDER TO SPECIFY FALSE STATEMENTS OR OMISSIONS.....	10
14	V.	ALL CLAIMS SHOULD BE DISMISSED AS PLAINTIFF HAS FAILED TO	
15		ADEQUATELY ALLEGED FALSITY.....	12
16	A.	The Efficacy Claims Amount to Disagreements Over Clinical Trial Design	
17		and Interpretation of Data, and, Therefore, Do Not Allege Any Material	
18		Misrepresentation.....	13
19	B.	The Safety Claims Do Not Allege Any Material Misrepresentation As the	
20		Detailed Data Disclosed in the Scientific Presentations Was Consistent	
21		With the Earlier Disclosures	17
22	VI.	THE SECTION 10(B) CLAIMS SHOULD BE DISMISSED BECAUSE	
23		PLAINTIFF HAS NOT ALLEGED SPECIFIC FACTS GIVING RISE TO	
24		STRONG INFERENCE OF SCIENTER	22
25	A.	Lack of insider sales is powerful evidence of lack of scienter.....	22
26	B.	Compensation, the need for capital and the importance of R788's success	
27		to Rigel do not give rise to a strong inference of scienter.....	23
28	C.	The more compelling inference from Plaintiff's allegations, taken as a	
29		whole, is that Defendants lacked scienter	23
30	VII.	PLAINTIFF'S SECTION 20(A) AND SECTION 15 CLAIMS SHOULD BE	
31		DISMISSED FOR FAILURE TO ALLEGED A PRIMARY VIOLATION OR THE	
32		REQUISITE "CONTROL.".....	24
33	VIII.	CONCLUSION	25

TABLE OF AUTHORITIES

	Page(s)
CASES	
<i>Ashcroft v. Iqbal</i> , 129 S. Ct. 1937 (2009)	8
<i>Basic Inc. v. Levinson</i> , 485 U.S. 224 (1988)	8, 9
<i>Borochoff v. GlaxoSmithKline PLC</i> , 2008 WL 2073421 (S.D.N.Y. May 9, 2008)	18
<i>Brody v. Transitional Hosps. Corp.</i> , 280 F.3d 997 (9th Cir. 2002)	9
<i>Clegg v. Cult Awareness Network</i> , 18 F.3d 752 (9th Cir. 1994)	8
<i>Constr. Laborers Pension Trust v. Neurocrine Biosciences, Inc.</i> , 2008 WL 2053733 (S.D. Cal. May 13, 2008)	23
<i>DeMarco v. DepoTech Corp.</i> , 149 F. Supp. 2d 1212 (S.D. Cal. 2001)	15
<i>DSAM Global Value Fund v. Altris Software, Inc.</i> , 288 F.3d 385 (9th Cir. 2002)	8
<i>Dura Pharmaceuticals, Inc. v. Broudo</i> , 544 U.S. 336 (2005)	16, 17
<i>Howard v. Everex Sys., Inc.</i> , 228 F.3d 1057 (9th Cir. 2000)	12
<i>In Re Ashworth, Inc. Sec. Litig.</i> , 2000 WL 33176041 (S.D. Cal. July 18, 2000)	22
<i>In re Apple Computer Sec. Litig.</i> , 886 F.2d 1109 (9th Cir. 1989), cert. denied, <i>Schneider v. Apple Computer, Inc.</i> , 496 U.S. 943 (1990)	15
<i>In Re Autodesk, Inc. Sec. Litig.</i> , 132 F. Supp. 2d 833 (N.D. Cal. 2000)	9
<i>In Re Copper Mountain Sec. Litig.</i> , 311 F. Supp. 2d 857 (N.D. Cal. 2004)	3, 13
<i>In Re Cornerstone Propane Partners, L.P. Sec. Litig.</i> , 355 F. Supp. 2d 1069 (N.D. Cal. 2005)	23

1	<i>In Re Foxhollow Tech., Inc. Sec. Litig.,</i> 2008 WL 2220600 (N.D. Cal. May 27, 2008)	9
2		
3	<i>In Re Harmonic Inc. Sec. Litig.,</i> 163 F. Supp. 2d 1079 (N.D. Cal. 2001)	24
4		
5	<i>In Re Intrabiotics Pharms. Inc., Sec. Litig.,</i> 2006 WL 2192109 (N.D. Cal. Aug. 1, 2006)	10, 18
6		
7	<i>In Re Levi Strauss & Co. Sec. Litig.,</i> 527 F. Supp. 2d 965 (N.D. Cal. 2007)	10
8		
9	<i>In Re Petsmart, Inc. Sec. Litig.,</i> 61 F. Supp. 2d 982 (D. Ariz. 1999)	23
10		
11	<i>In Re Pixar, Inc. Sec. Litig.,</i> 450 F. Supp. 2d 1096 (N.D. Cal. 2006)	22
12		
13	<i>In Re Silicon Graphics, Inc. Sec. Litig.,</i> 183 F.3d 970 (9th Cir. 1999)	9
14		
15	<i>In Re Stac Elecs. Sec. Litig.,</i> 89 F.3d 1399 (9th Cir. 1996)	8, 10
16		
17	<i>In Re Tibco Software Securities Litigation, In re</i> 2006 WL 1469654 (N.D. Cal. May 25, 2006)	22
18		
19	<i>In Re Vantive Corp. Sec. Litig.,</i> 283 F.3d 1079 (9th Cir. 2002)	9
20		
21	<i>Lilley v. Charren,</i> 936 F. Supp. 708 (N.D. Cal. 1996)	25
22		
23	<i>Lipton v. Pathogenesis Corp.,</i> 284 F.3d 1027 (9th Cir. 2002)	23, 24
24		
25	<i>McHenry v. Renne,</i> 84 F.3d 1172 (9th Cir. 1996)	12
26		
27	<i>Metzler Inv. GMBH v. Corinthian Colleges, Inc.,</i> 540 F.3d 1049 (9th Cir. 2008)	22
28		
29	<i>Noble Asset Mgmt. v. Allos Therapeutics, Inc.,</i> 2005 WL 4161977 (D. Colo. Oct. 20, 2005)	15
30		
31	<i>Oran v. Stafford,</i> 226 F.3d 275 (3rd Cir. 2000)	18
32		
33	<i>Padnes v. Scios Nova Inc.,</i> 1996 WL 539711 (N.D. Cal. Sept. 18, 1996)	14, 15, 16, 18
34		

1	<i>Robertson v. Dean Witter Reynolds, Inc.</i> , 749 F.2d 530 (9th Cir. 1984).....	8
2		
3	<i>Ronconi v. Larkin</i> , 253 F.3d 423, 430 (9th Cir. 2001).....	13
4		
5	<i>Tellabs, Inc. v. Makor Issues & Rights, Ltd.</i> , 551 U.S. 308 (2007).....	10
6		
7	<i>TSC Indus., Inc. v. Northway, Inc.</i> , 426 U.S. 438 (1976).....	8
8		
9	<i>Twinde v. Threshold Pharms., Inc.</i> , 2008 WL 2740457 (N.D. Cal. July 11, 2008).....	16
10		
11	<i>Wenger v. Lumisys, Inc.</i> , 2 F. Supp. 2d 1231 (N.D. Cal. 1998)	12
12		
13	<i>Yourish v. Cal. Amplifier</i> , 191 F.3d 983 (9th Cir. 1999).....	13
14		
15	STATUTES AND RULES	
16	15 U.S.C. §§ 77k(a), 77l(a)(2)	10
17		
18	15 U.S.C. § 78u-4(b).....	1, 9
19		
20	15 U.S.C. § 78u-4(b)(1)	9
21		
22	15 U.S.C. § 78u-4(b)(2)	9
23		
24	15 U.S.C. § 78u-4(b)(3)	9
25		
26	15 U.S.C. § 78u-5(i)(1)(B).....	13
27		
28	Fed. R. Civ. P. 9(b)	8
	Fed. R. Civ. P. 12(b)(6).....	8

1 NOTICE OF MOTION AND MOTION TO DISMISS**2 TO ALL PARTIES AND THEIR ATTORNEYS OF RECORD:**

3 PLEASE TAKE NOTE that on April 9, 2010, at 9:00 a.m., or as soon thereafter as this
 4 motion may be heard, defendant Rigel Pharmaceuticals, Inc. (“Rigel” or the “Company”) and
 5 defendants James M. Gower, Ryan D. Maynard, Donald G. Payan, Raul R. Rodriguez, Elliott B.
 6 Grossbard, Jean Deleage, Bradford S. Goodwin, Gary A. Lyons, Walter H. Moos, Hollings C.
 7 Renton, Peter S. Ringrose, and Stephen A. Sherwin (“Individual Defendants,” and, together with
 8 Rigel, “Defendants”) will and hereby do move to dismiss with prejudice all claims asserted
 9 against them in Plaintiff’s Consolidated Amended Complaint (the “CAC”). This motion is based
 10 on the accompanying Memorandum of Points and Authorities and Appendix; Defendants’
 11 Request for Judicial Notice; the Declaration of William S. Freeman and exhibits thereto
 12 (“Freeman Decl.”); all pleadings and papers on file in this action; and such other matters as may
 13 be presented to the Court at the time of the hearing.

14 STATEMENT OF RELIEF SOUGHT

15 Defendants seek an order dismissing the CAC with prejudice pursuant to Rules 9(b) and
 16 12(b)(6) of the Federal Rules of Civil Procedure and the Private Securities Litigation Reform Act
 17 (15 U.S.C. § 78u-4(b)) (“PSLRA”) for failing to state a claim upon which relief can be granted
 18 and failing to meet the pleading requirements of Rule 9(b) and the PSLRA.

19 STATEMENT OF ISSUES TO BE DECIDED

20 1) With respect to all claims for relief, whether the CAC should be dismissed because
 21 Plaintiff has failed to comply with the Court’s Order directing it to clearly identify the omissions
 22 or misrepresentations forming the basis for its claims.

23 2) With respect to all claims for relief, whether Plaintiff’s criticisms of the design of
 24 Rigel’s clinical trial and Rigel’s interpretation of the resulting data is sufficient to allege a
 25 material misstatement or omission.

26 3) With respect to all claims, whether Plaintiff has pled with the required particularity
 27 that Defendants’ statements to investors regarding side effects noted during the clinical trial were
 28 materially false or misleading, when Defendants later provided more detailed, but consistent,

1 patient data at a scientific conference.

2 4) With respect to the first and second claims for relief, whether Plaintiff has
 3 adequately alleged that those statements were made with a strong inference of scienter when no
 4 officer Defendant sold a single share of stock during the alleged class period.

5 5) With respect to the second and fifth causes of action, whether Plaintiff has
 6 adequately pled that Defendants are liable as control persons when they failed to allege a primary
 7 violation or to plead facts showing any Defendant's ability to control any other Defendant.

8 **MEMORANDUM OF POINTS AND AUTHORITIES**

9 **I. INTRODUCTION AND SUMMARY OF ARGUMENT.**

10 In its December 21, 2009 Order Granting Defendants' Motion to Dismiss ("Order"), this
 11 Court dismissed the Consolidated Complaint ("CC"), holding that Plaintiff had not "fulfilled its
 12 responsibility" to identify any false statements with particularity. (Order at 11:24-12:1.) The
 13 Court directed that if Plaintiff wished to file a new complaint, it "should *clearly identify* which
 14 *specific* statements within the documents or block quotes it contends are false or misleading and
 15 which *specific* affirmative public statement or statements it alleges were rendered misleading by
 16 any alleged omissions." (Order at 12:7-10 (emphasis in original).)

17 In response, Plaintiff filed a "Consolidated Amended Complaint" ("CAC") that is 26
 18 pages and 64 paragraphs longer than the CC, but still does not comply with the Court's clear and
 19 simple instruction. Nowhere is there a straightforward, concise listing of allegedly false
 20 statements or omissions by Rigel Pharmaceuticals, Inc. ("Rigel" or "the Company") or any of the
 21 Individual Defendants. For this reason alone, the CAC should be dismissed.

22 The CAC's problems, however, are more than structural. Plaintiff has failed to cure any
 23 of the serious problems described in Defendants' previous motion to dismiss. Plaintiff's claims
 24 relating to patient safety data still fail to establish that any Defendant made a material false
 25 statement when the initial clinical trial results were announced. Defendants' later statements,
 26 although more detailed, were entirely consistent with the earlier announcements. Furthermore,
 27 Plaintiff has once again failed to sufficiently allege *scienter*, relying instead on conclusory
 28 allegations of intent and legally insufficient allegations of motive.

1 Perhaps hoping that the Court will overlook its failure to cure these defects, Plaintiff has
 2 advanced a new argument in the CAC by submitting a declaration by a retained statistician who
 3 disagrees with the design of the underlying clinical trial and with Rigel's interpretation of its
 4 results, even as he acknowledges that Rigel's interpretation was published in a leading peer-
 5 reviewed medical journal. Under settled principles of law, disagreements of this kind do not
 6 establish that any of Defendants' statements about the trial were false or misleading.

7 For all of these reasons, the complaint should be dismissed with prejudice.

8 **II. STATEMENT OF ALLEGATIONS AND FACTS SUBJECT TO JUDICIAL NOTICE.**

9 **A. The Parties.**

10 The lead plaintiff, Inter-Local Pension Fund GCC/IBT, claims to have purchased Rigel
 11 stock traceable to the Company's February 6, 2008 secondary stock offering. (¶ 26.)¹ Plaintiff
 12 seeks to represent a class of all persons who purchased Rigel stock between December 13, 2007
 13 and February 3, 2009. (¶ 1.) Defendant Rigel is a clinical-stage drug development company that
 14 discovers and develops novel, small-molecule drugs for the treatment of
 15 inflammatory/autoimmune diseases, certain cancers and metabolic disease. (¶ 2.) The Individual
 16 Defendants are officers and directors of Rigel. (¶¶ 29-42.)²

17 **B. Rheumatoid Arthritis, R788 and the Phase IIa Clinical Trial.**

18 Rheumatoid arthritis ("RA") is an autoimmune disease characterized by chronic
 19 inflammation that affects the joints and other tissues. (¶¶ 3, 50.) R788, the drug at the center of
 20 this case, is unique in the treatment of RA in that it is designed to interrupt the cellular signaling
 21 at the trigger point of inflammation, thereby stopping the progression of the disease. (Freeman
 22 Decl.³ Ex. D (12/13/07 8-K/PR, CAC ¶ 4, 60).)

23 In 2006, Rigel initiated enrollment and dosing for a Phase IIa clinical trial of R788.

24 ¹ All paragraph references are to the CAC unless otherwise indicated.

25 ² Also named as defendants are the four underwriters of Rigel's February 2008 secondary stock
 26 offering (¶¶ 43-46), who are filing a separate joinder.

27 ³ All of the exhibits to the Freeman Declaration are SEC filings, documents referenced in the
 28 CAC and/or documents available to the market whose authenticity cannot be questioned, and are
 the subject of Defendants' Request for Judicial Notice. *See, e.g., In re Copper Mountain Sec.
 Litig.*, 311 F. Supp. 2d 857, 863 (N.D. Cal. 2004).

1 (¶ 53.) The clinical trial was a multi-center, randomized, double-blind, placebo-controlled,
 2 ascending dose study involving 189 patients in the United States and Mexico. (¶¶ 3, 52.) Patients
 3 were placed into cohorts receiving either 50, 100 or 150 mg of R788 orally twice daily. (¶ 52.)
 4 The primary objective of the study was to determine the preliminary efficacy and tolerability of
 5 three different dosing regimens of R788 as compared with a placebo over a 12-week period in
 6 patients with active RA despite therapy with methotrexate. (Freeman Decl. Ex. M (Nov. 2008
 7 Article, CAC ¶¶ 106, 110, 112, 113) at 3310.) Rigel measured efficacy for each participant
 8 based on the American College of Rheumatology criteria, known as ACR scores. The ACR
 9 measurements include improvement in subjective factors, such as a patient's reported pain score
 10 and the global assessment of patients and physicians of disease activity. (See *id.*) ACR scores
 11 also include objective factors, such as the change in C-reactive proteins in the patients' blood.
 12 (Freeman Decl. Ex. D (12/13/07 Form 8-K/PR) at 3.) The primary efficacy endpoint for the trial
 13 (that is, the key measure that would determine success or failure of the trial) was the ACR 20
 14 percent improvement criteria ("ACR20"). (¶ 52.)

15 **C. December 2007: Initial Reports of the Results of the Phase IIa Trial.**

16 On December 13, 2007, Rigel announced the key or "top-line" results of the trial,
 17 including, most importantly, the fact that R788 had demonstrated statistically significant results in
 18 treating RA. (¶ 60.) Rigel disclosed that the groups treated with 100 mg and 150 mg doses
 19 showed higher ACR20, ACR50 and ACR70 response rates than the placebo groups, and that the
 20 onset of the effect occurred as early as one week after initiation of therapy. (*Id.*) Rigel also
 21 reported clinically meaningful "key safety results" in tabular form. (*Id.*)

22 That same day, Rigel held a conference call with financial analysts regarding the Phase IIa
 23 results. (¶ 61; Freeman Decl. Ex. E (12/13/07 trans.) at 1.) During the call, Dr. Grossbard,
 24 Rigel's Chief Medical Officer, stated that the 100 mg and 150 mg groups had "impressive and
 25 statistically significant improvements over placebo." (¶ 61; Freeman Decl. Ex. E (12/13/07
 26 trans.) at 3.) He stated that safety would be "a close focus of the future program" for R788, and
 27 summarized some of the key safety results. (*Id.*) Dr. Grossbard said that he and the principal
 28 investigator were writing a paper and that the publication of that paper would be the next

1 significant statement about the results of the study. (Freeman Decl. Ex. E (12/13/07 trans.) at 6.)

2 **D. February 2008: Rigel's Secondary Offering.**

3 Rigel filed a Form S-3ASR Registration Statement and Form 424B3 Prospectus with the
 4 SEC on January 24, 2008 in connection with a secondary stock offering. (¶ 148.) Rigel also filed
 5 a Form 424B5 Prospectus on February 1, 2008. (¶ 149.) The Registration Statement
 6 incorporated by reference, among other documents, Rigel's Form 8-K filed on December 13,
 7 2007, attaching the press release announcing the results of the Phase IIa trial. (¶ 150.)

8 **E. October-November 2008: Clinical Presentation of Trial Results.**

9 On October 27, 2008, Rigel presented detailed clinical data from its Phase IIa trial at the
 10 American College of Rheumatology Annual Scientific Meeting ("ACR Meeting") and during an
 11 investor conference call, which was closely followed by the publication of the detailed clinical
 12 trial data in the November 2008 issue of *Arthritis & Rheumatism* ("Nov. 2008 Article"). (¶ 170;
 13 Freeman Decl. Ex. M (Nov. 2008 Article, CAC ¶¶ 106, 110, 112, 113) (e-published Oct. 30,
 14 2008).) According to Plaintiff, *Arthritis & Rheumatism* is "considered by many to be among the
 15 leading peer-reviewed medical journals for" rheumatic diseases. (CAC Ex. A, Declaration of
 16 Daniel A. Bloch at 1.) In the November 2008 Article, the Company repeated the primary findings
 17 that had been disclosed in 2007 and provided additional detailed data, including a breakdown of
 18 the data based on whether the patients lived in the United States or Mexico. (Freeman Decl. Ex.
 19 M (Nov. 2008 Article).)

20 The Company also discussed the adverse events that certain patients in the trial had
 21 experienced. With respect to liver enzymes, Dr. Grossbard reported that R788 had a "liver
 22 signal," but "it's just not a very significant one so far." (Freeman Decl. Ex. I (10/27/08 trans.) at
 23 3.) With respect to neutropenia, he observed that "I just don't think it's been an important clinical
 24 effect. Certainly not from an infectious disease point of view." (*Id.* at 18.) With respect to blood
 25 pressure, Dr. Grossbard noted that investigators wrote "hypertension" on the case report forms for
 26 five patients in the two high dose groups. (¶ 99.) He stated that there was an average increase in
 27 blood pressure of about 4 to 5 mm systolic and 2 or 3 mm diastolic relative to baseline in the 100
 28 mg group. (*Id.*) In the 150 mg group, the increase was about 8 mm systolic and 4 mm diastolic

1 relative to baseline. (*Id.*) During a Rigel conference call on November 3, 2008, Mr. Gower,
 2 Rigel's CEO, pointed out that "the response we've had from the rheumatology community has
 3 been overwhelming that [blood pressure increase] is not a clinical issue." (Freeman Decl. Ex. N
 4 (11/03/08 trans.) at 9.)

5 During the investor conference call, Dr. Grossbard also fielded questions concerning an
 6 unfounded rumor that R788 prolonged the "QTc interval" of the heart, which can be associated
 7 with fatal cardiac arrhythmias. (Freeman Decl. Ex. I (10/27/08 trans.) at 20, 23.) Dr. Grossbard
 8 denied the rumor (*id.*), although analysts later suggested that speculation about QTc prolongation
 9 may have pushed Rigel's stock lower. (*See, e.g.*, Freeman Decl. Ex. L (10/28/08 Oppenheimer,
 10 CAC ¶¶ 107, 108, 111, 135, 173) at 1, 4 ("Speculation about QTc prolongation circled at the
 11 [ACR] conference, which likely contributed to some of the pressure on RIGL shares.").)⁴

12 The November 2008 Article presented the clinical data in exhaustive detail and discussed
 13 the results. (*See* Freeman Decl. Ex. M (Nov. 2008 Article).) Included in the article were tables
 14 with highly detailed analyses of the data. (*Id.* at 3311-15.) Table 4 listed all adverse events that
 15 occurred in three percent or more of the patients in any treatment group. Those adverse events
 16 (or side effects) included abdominal pain, urinary and upper respiratory tract infections, headache,
 17 dizziness, fatigue, edema, rash, cough, increased alkaline phosphatase, anemia, diarrhea
 18 (regardless of the severity), GI effects (including nausea, gastritis and dyspepsia, regardless of
 19 severity), neutropenia (whether or not dose reduction was required), hypertension (regardless of
 20 severity), and increased ALT levels (defined as greater than 1.2 times the upper limit of normal,
 21 or "1.2XULN"). (*Id.* at 3315.) While this data was more detailed and comprehensive than the
 22 top-line data previously disclosed by the Company in 2007, it was fully consistent in every
 23 respect with the earlier disclosures.

24 Plaintiff seeks to recover damages based on the drop in Rigel's stock price on October 27,
 25 2008, following Rigel's discussion of the Phase IIa trial at the ACR meeting and the initiation of

26 ⁴ On February 3, 2009, Rigel reported the results from a later study specifically designed to
 27 address the QTc issue which found that "there were no significant effects on the QT/QTc
 28 intervals of the participants in either the 100mg bid or the 300mg bid R788 dosage groups."
 (Freeman Decl. Ex. O (2/3/09 8-K/PR) at 2.)

1 the QTc rumor. (¶ 18.)

2 **F. Rigel's Statements Regarding Potential Partnering Opportunities.**

3 In its 2007 Form 10-K, filed on March 7, 2008, Rigel stated that one of its strategies for
 4 future funding was to establish “strategic collaborations” with other companies to develop and
 5 market products. (¶ 132; Freeman Decl. Ex. G (Excerpts from 2007 Form 10-K) at 2.) The 2007
 6 Form 10-K contained detailed “safe harbor” language regarding forward-looking statements,
 7 which included warnings that statements about future plans were subject to uncertainty. (*Id.*; *see*
 8 *also* Appendix, ¶ 3 (reproducing relevant “safe harbor” warnings).) At the October 27, 2008
 9 ACR Meeting, Mr. Gower commented that Rigel was “still on track for . . . putting the
 10 partnership in place as early as the early part of next year” and “ideally a few months before we
 11 go to the end-of-Phase 2b meeting and start the Phase 3s, which starts in the second half of next
 12 year.” (¶ 134). This presentation was also prefaced by a “safe harbor” warning. (*See* Freeman
 13 Decl. Ex. I (10/27/08 trans.) at 1.) On a November 3, 2008 conference call, Mr. Gower stated,
 14 “We expect to establish a collaboration partnership to further [the development and
 15 commercialization of R788], and that in fact is going quite well.” (Freeman Decl. Ex. N (11/3/08
 16 trans.) at 5.) Once again, a detailed “safe harbor” warning was given. (*See* Appendix, ¶ 5.)

17 On February 3, 2009, Rigel announced that it was delaying partnership discussions for
 18 R788 until after results from the Phase IIb clinical trials become available. (¶ 20.) At that time,
 19 Mr. Gower stated that “postponing the partnership for R788, pending the forthcoming clinical
 20 trial results, will better position us to secure an optimal partnership arrangement for R788.”
 21 (Freeman Decl. Ex. O (2/3/09 8-K/PR) at 1.)

22 On February 16, 2010, Rigel announced that it had entered into an exclusive worldwide
 23 license agreement with AstraZeneca for the development of R788, pursuant to which AstraZeneca
 24 will pay Rigel an up-front payment of \$100 million and up to an additional \$345 million if
 25 specified development and regulatory milestones are achieved. (Freeman Decl. Ex. S.) The
 26 Company also announced that, under the partnership agreement, it will be eligible to receive an
 27 additional \$800 million if certain sales targets are met as well as significant royalties on
 28 worldwide sales. (*Id.*)

Notwithstanding Rigel's "safe harbor" warnings and the subsequent realization of Rigel's partnership plans, Plaintiff seeks to recover additional damages based on the drop in Rigel's stock from \$7.17 to \$6.50 on February 3, 2009. (¶¶ 20, 187, 189.)

III. LEGAL STANDARDS.

Rule 12(b)(6) of the Federal Rules of Civil Procedure. The Court must dismiss a complaint under Rule 12(b)(6) where it fails to allege facts sufficient to support a cognizable legal claim. *Robertson v. Dean Witter Reynolds, Inc.*, 749 F.2d 530, 533-34 (9th Cir. 1984). While a court must accept all well-pleaded factual allegations as true, it need not consider unsupported, conclusory allegations. *In re Stac Elecs. Sec. Litig.*, 89 F.3d 1399, 1403 (9th Cir. 1996). Nor should a court accept legal or factual allegations based on unwarranted deductions or unreasonable inferences, or allegations that contradict materials properly subject to judicial notice. *See Clegg v. Cult Awareness Network*, 18 F.3d 752, 754-55 (9th Cir. 1994). The Supreme Court recently clarified these standards to confirm that a court should not accept “[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements.” *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009). Dismissal is appropriate where the court determines that the facts as alleged do not amount to a plausible claim. *Id.*

Section 10(b) of the Securities Exchange Act of 1934 and Rule 10b-5. To state a claim under Section 10(b) and Rule 10b-5 promulgated thereunder, a plaintiff must allege: (1) a misstatement or omission (2) of material fact (3) made with scienter (4) on which she relied (5) which proximately caused plaintiff's injury. *DSAM Global Value Fund v. Altris Software, Inc.*, 288 F.3d 385, 388 (9th Cir. 2002) (citation omitted). For an omitted fact to be "material," "there must be a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available." *Basic Inc. v. Levinson*, 485 U.S. 224, 231-32 (1988) (quoting *TSC Indus., Inc. v. Northway, Inc.*, 426 U.S. 438, 449 (1976)). In securities fraud cases, Rule 9(b) of the Federal Rules of Civil Procedure further requires that "a party must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). A plaintiff must plead "specific facts regarding the alleged fraudulent activity, such as the time, date, places, content of

1 each fraudulent representation, the reasons that the representation is false, and the identity of the
 2 person or persons engaged in the fraud.” *In re Autodesk, Inc. Sec. Litig.*, 132 F. Supp. 2d 833,
 3 839 (N.D. Cal. 2000) (citation omitted).

4 The PSLRA significantly heightens the “particularity” requirement of Rule 9(b) by
 5 imposing stringent requirements for pleading falsity and scienter in private securities litigation.
 6 15 U.S.C. § 78u-4(b)(1)-(3). To satisfy these heightened pleading requirements with regard to
 7 falsity, a plaintiff must identify (1) each statement alleged to have been misleading, (2) the reason
 8 or reasons why the statement is misleading, and (3) if an allegation regarding the statement or
 9 omission is made on information and belief, all facts on which that belief is formed. 15 U.S.C. §
 10 78u-4(b)(1); *In re Vantive Corp. Sec. Litig.*, 283 F.3d 1079, 1085 (9th Cir. 2002). If a plaintiff is
 11 alleging an omission of material fact, then the plaintiff must show that the defendant had a duty to
 12 disclose the omitted information. *Basic*, 485 U.S. at 239 n.17 (“Silence, absent a duty to disclose,
 13 is not misleading under Rule 10b-5.”). There is no duty to disclose material information simply
 14 because it exists. *In re Foxhollow Techs., Inc., Sec. Litig.*, 2008 WL 2220600, at *16 (N.D. Cal.
 15 May 27, 2008). Rather, “[t]o be actionable under the securities laws, an omission must be
 16 misleading; . . . it must affirmatively create an impression of a state of affairs that differs in a
 17 material way from the one that actually exists.” *Brody v. Transitional Hosps. Corp.*, 280 F.3d
 18 997, 1006 (9th Cir. 2002). If a statement is not false or misleading but merely incomplete, it is
 19 not actionable under the securities laws. *Id.*

20 A complaint must also “state with particularity facts giving rise to a strong inference that
 21 the defendant acted with the required state of mind.” 15 U.S.C. § 78u-4(b)(2). In the Ninth
 22 Circuit, a plaintiff must plead “deliberately reckless or conscious misconduct” by the defendant.
 23 *In re Silicon Graphics Inc. Sec. Litig.*, 183 F.3d 970, 974 (9th Cir. 1999). To establish a strong
 24 inference of deliberate recklessness, “the plaintiff must plead ‘a highly unreasonable omission,
 25 involving not merely simple, or even inexcusable negligence, but an extreme departure from the
 26 standards of ordinary care, and which presents a danger of misleading buyers or sellers that is
 27 either known to the defendant or is so obvious that the actor must have been aware of it.’” *Zucco
 28 Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 991 (9th Cir. 2009) (citation omitted).

1 Moreover, a complaint will survive a motion to dismiss only “if a reasonable person would deem
 2 the inference of scienter cogent and at least as compelling as any opposing inference one could
 3 draw from the facts alleged.” *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 324
 4 (2007). A court must take into account plausible nonculpable explanations for the defendant’s
 5 conduct. *Id.*

6 **Sections 11 and 12(a)(2) of the Securities Act of 1933.** To state a claim under Sections
 7 11 and 12(a)(2), a plaintiff must allege the purchase of securities in an offering pursuant to a
 8 written prospectus that contained a material omission or misrepresentation. *In re Levi Strauss &*
 9 *Co. Sec. Litig.*, 527 F. Supp. 2d 965, 974-75, 980 (N.D. Cal. 2007) (citations omitted); 15 U.S.C.
 10 §§ 77k(a), 77l(a)(2).

11 The particularity requirements of Rule 9(b) apply to claims brought under Sections 11 and
 12 12(a)(2) where, as here, a plaintiff’s claims are based on an allegedly fraudulent course of
 13 conduct, or are “grounded in fraud.” *In re Intrabiotics Pharm., Inc. Sec. Litig.*, 2006 WL
 14 2192109, at *16 (N.D. Cal. Aug. 1, 2006); *Stac Elecs.*, 89 F.3d at 1404-05. A plaintiff’s
 15 “nominal” disclaimer of fraud, such as the perfunctory statement in paragraph 109 of the CAC, is
 16 “unconvincing where the gravamen of the complaint is plainly fraud and no effort is made to
 17 show any other basis for the claims” *Stac Elecs.*, 89 F.3d at 1405 n.2.

18 **IV. THE CAC SHOULD BE DISMISSED AS PLAINTIFF FAILED TO FOLLOW THE COURT’S
 19 ORDER TO SPECIFY FALSE STATEMENTS OR OMISSIONS.**

20 The Court gave clear instructions to Plaintiff in the event it decided to file a new
 21 complaint: Plaintiff was to identify the specific statements it contends were false and the specific
 22 affirmative statements it contends were rendered misleading by any alleged omissions. (Order at
 23 12:7-10.) Plaintiff has failed this simple requirement. Rather, Plaintiff has offered the 89-page,
 24 239-paragraph CAC, which incorporates all of the failings of the previous pleading and actually
 25 compounds them by adding new claims that are not clearly tied to the existing ones. Rather than
 26 attempting to reconstruct its house of cards, Plaintiff has tacked on a new wing.

27 For example, the Court initially noted that Paragraphs 48 and 49 of the CC set forth
 28 allegedly false and misleading statements, but that it was impossible to know what statements

were allegedly false because these paragraphs “contain[ed] extensive block quotes with multiple statements.” (Order at 10:21-22.) Plaintiff’s sole response to this observation was to repeat paragraphs 48 and 49 of the CC in their entirety as paragraphs 60 and 61 of the CAC, merely adding to each paragraph the following: “(false and misleading statements are in bold and italics.)” This is hardly an improvement, as the same paragraphs in the CC already had plenty of bold, italicized text. Moreover, the parenthetical statement is incorrect, as the bolded and italicized text includes raw numbers from clinical trial results, such as the total numbers of patients in each treatment group, that Plaintiff has never claimed to be false.⁵

The Court next observed that Plaintiff attempted to allege various non-disclosures in paragraphs 54, 55, 61, 68, 71, 73 and 74 of the CC, but “fail[ed] to identify what affirmative public statement or statements the alleged omissions rendered misleading.” (Order at 10:27-11:6.) Plaintiff’s answer to these shortcomings ranges from non-responsiveness to obfuscation. For example, paragraphs 71, 73 and 74 of the CC, relating to alleged nondisclosures of clinical trial results concerning neutropenia, upper gastrointestinal tract disorders and diarrhea, have been repledged, virtually verbatim,⁶ as paragraphs 110 to 113 of the CAC. Plaintiff has still failed to state why the original disclosures were incomplete or misleading.

In paragraphs 55 to 60 of the CC, Plaintiff had alleged that while Rigel reported overall results of its clinical trial in December 2007, it failed to break out the results for patients in Mexico and the U.S. until October 2008, which “may have overstated the dose response.” That allegation is carried over into paragraphs 70 to 73 of the CAC. And it still misses the mark as Rigel never touted a “dose response.” Indeed, in its original December 2007 announcement, the Company stated that “efficacy results for the 100 and 150 mg dose groups were fairly comparable.” (CAC ¶ 60 (emphasis omitted).)

In one final example, paragraphs 68 to 70 of the CC, dealing with disclosures of increases in liver enzymes, have been repledged, virtually unchanged, as paragraphs 106 to 108 of the

⁵ See, e.g., CAC ¶ 60 at 15:15-19.

⁶ Plaintiff did make one change in these paragraphs, substituting digits for words when reporting numbers, e.g. “5” instead of “five.” Compare, e.g., CAC ¶ 110 with CC ¶ 71.

1 CAC. The only new falsity allegation relating to liver enzymes is paragraph 109, which claims
 2 that, in December 2007, Rigel only disclosed liver enzyme elevations at the level of three times
 3 the upper limit of normal (“3XULN”) whereas in an earlier study it had disclosed elevations at a
 4 level of 2XULN. There is no allegation that the data disclosed in either instance were false; the
 5 CAC alleges only that the earlier disclosure “set expectation [sic]” for later disclosures. (¶ 109.)
 6 This assertion does not even approach an adequate allegation of falsity.

7 The CAC is, if anything, more convoluted and impenetrable than its predecessor. “In the
 8 context of securities class action complaints, courts have repeatedly lamented plaintiffs’ counsels’
 9 tendency to place ‘the burden [] on the reader to sort out the statements and match them with the
 10 corresponding adverse facts to solve the ‘puzzle’ of interpreting Plaintiffs’ claims.’” *Wenger v.*
 11 *Lumisys, Inc.*, 2 F. Supp. 2d 1231, 1244 (N.D. Cal. 1998) (citations omitted). Plaintiff has failed
 12 to comply with the Court’s Order by not clearly identifying the allegedly false and misleading
 13 statements and omissions. Where plaintiff has ignored a court order and filed a complaint that
 14 “requires a laborious deconstruction and reconstruction of a great web of scattered, vague,
 15 redundant, and often irrelevant allegations,” dismissal is appropriate. *Wenger*, 2 F. Supp. 2d at
 16 1243; *see also McHenry v. Renne*, 84 F.3d 1172, 1178 (9th Cir. 1996). That is the case here.

17 **V. ALL CLAIMS SHOULD BE DISMISSED AS PLAINTIFF HAS FAILED TO ADEQUATELY**
 18 **ALLEGED FALSITY.**

19 Plaintiff fails to adequately allege that any statement by any Defendant was false, much
 20 less materially false, when made.⁷ Although the CAC’s emphasis has shifted, Plaintiff now
 21 appears to make two types of allegations: (1) that, based on an after-the-fact analysis by
 22 Plaintiff’s retained statistician, Rigel’s December 2007 disclosures overstated the efficacy of the
 23 drug (hereafter, the “Efficacy Claims”); and (2) Rigel’s December 2007 disclosure of top-line
 24 patient data materially misrepresented safety risks that were revealed by the consistent, but more
 25 detailed patient data was provided at the ACR meeting (hereafter, the “Safety Claims”). Both sets
 26

27 ⁷ Plaintiff has also failed to allege that defendants Maynard and Payan made or were involved in
 28 the preparation of any of the challenged statements. As a result, they cannot be primarily liable
 under Section 10(b). *Howard v. Everex Sys., Inc.*, 228 F.3d 1057, 1061 n.5 (9th Cir. 2000).

1 of allegations fail under the PSLRA.⁸

2 **A. The Efficacy Claims Amount to Disagreements Over Clinical Trial Design**
 3 **and Interpretation of Data, and, Therefore, Do Not Allege Any Material**
 4 **Misrepresentation.**

5 In its prior pleading, Plaintiff had alleged that Rigel had “failed to report ACR response
 6 data by country” and that this was important because analysts noted that “higher response rates by
 7 Mexican patients *may have* overstated the dose response.” (CC, ¶¶ 55, 59 (emphasis added).) In
 8 response to Defendants’ argument that such an equivocal allegation hardly established a false
 9 statement, Plaintiff has changed the focus of its argument by attaching the declaration of a
 10 retained statistician, Daniel Bloch.⁹ Mr. Bloch opines that the design of Rigel’s clinical trial was
 11 flawed because, among other things, the sample sizes were so small that “sample size estimates”
 12 were calculated using an incorrect formula that overstated the power of the study to detect
 13 treatment differences between study groups. (Bloch Decl. (Ex. A to CAC) at 13-16.) Mr. Bloch
 14 also opines that the resulting data was improperly analyzed. (*Id.* at 3-12.)

15 Based solely on the Bloch Declaration, Plaintiff alleges that Defendants’ December 2007
 16 statements that the Phase IIa trial results were statistically significant were false because
 17 Defendants (1) improperly pooled the data from the Mexico and U.S. sites (¶ 75); (2) used an
 18 improper statistical analysis for a trial with a small sample size (¶ 78); and (3) failed to

19 ⁸ Plaintiff also alleges fraud based on Mr. Gower’s statements in October and November of 2008
 20 that Rigel was “on track for putting a partnership in place in the early part of 2009.” (¶ 134.) But
 21 statements regarding Rigel’s hopes for a partnership to further develop R788 are not rendered
 22 false simply by the later delay of such a partnership. *See Yourish v. Cal. Amplifier*, 191 F.3d 983,
 23 997 (9th Cir. 1999). Nor does Plaintiff allege any facts showing that, in October and November
 24 of 2008, Defendants did not in fact anticipate a partnership in early 2009. *See Ronconi v. Larkin*,
 25 253 F.3d 423, 430 (9th Cir. 2001) (optimistic prediction about a merger did not come to pass
 26 “does not raise a strong inference that defendants actually knew their forward looking statements
 27 to investors were false or misleading when made”). Moreover, Mr. Gower’s comments about
 Rigel’s partnership aspirations were forward-looking statements concerning “plans and objectives
 28 of management” and therefore protected under the PSLRA’s safe harbor. 15 U.S.C. § 78u-
 5(i)(1)(B). The statements were identified as forward looking when made and accompanied by
 meaningful cautionary language. (See Appendix, ¶ 4.) Accordingly, those statements are well
 within the PSLRA’s safe harbor and not actionable. *See, e.g., In re Copper Mountain Sec. Litig.*,
 311 F. Supp. 2d 857, 880-82 (N.D. Cal. 2004).

9 Defendants have filed a separate motion to strike Mr. Bloch’s declaration based on the
 procedural impropriety inherent in attaching the declaration as part of Plaintiff’s pleadings.

1 statistically correct for the “multiple comparisons problem.” (¶ 80.)

2 Importantly, Mr. Bloch acknowledges that Rigel based its disclosures on statistical
 3 analyses that were published in *Arthritis and Rheumatism*, “among the leading specialized peer-
 4 reviewed journals for” rheumatic diseases. (Bloch Decl. (Ex. A to CAC) at 1.) By contrast,
 5 Plaintiff is unable to assert that Mr. Bloch’s analysis has been peer-reviewed or published in a
 6 peer-reviewed journal. In essence, Plaintiff’s claim now boils down to the assertion that the
 7 Court should accept the claims of its non-peer-reviewed, retained statistician that the peer-
 8 reviewed work of Rigel’s study authors was intentionally misleading.

9 These new allegations fail because, under settled law, disagreements over study design
 10 and interpretation are insufficient to allege a material false statement. When a company
 11 accurately reports the findings of a clinical study, it is under no obligation to second-guess the
 12 study or how best to interpret the data. *See Padnes v. Scios Nova Inc.*, 1996 WL 539711, at *5
 13 (N.D. Cal. Sept. 18, 1996). In *Padnes*, the plaintiff alleged that defendants failed to disclose
 14 certain details of the study that plaintiff characterized as “design defects,” and that defendants
 15 should have included different measurements of the study’s outcome. *Id.* at *5. The plaintiff also
 16 alleged that defendants’ statements that the study demonstrated statistical significance were false
 17 because plaintiff “interpret[ed] the study data as failing to show that [the drug] improved kidney
 18 function.” *Id.*

19 This Court held that the company’s decision to provide top-line data and not minute
 20 details was an exercise of judgment, not securities fraud. *Id.* As Judge Patel explained:

21 Medical researchers may well differ with respect to what constitutes
 22 acceptable testing procedures, as well as how best to interpret data
 23 garnered under various protocols. The securities laws do not
 24 impose a requirement that companies report only information from
 25 optimal studies, even if scientists could agree on what is optimal.
 26 Nor do they require that companies who report information from
 27 imperfect studies include exhaustive disclosures of procedures
 28 used, including alternatives that were not utilized and various
 opinions with respect to the effects of these choices on the
 interpretation of the outcome data.

Defendants, like any other company wishing to publicly discuss the
 results of a scientific study, had to make a judgment as to which
 specific bits of information about the study and its conclusions to
 disclose. With the advantage of hindsight, defendants’ judgment as

1 to which information to disclose is subject to challenge; however,
 2 this does not amount to “facts explaining why the difference
 3 between the earlier and later statements is not merely the difference
 between two permissible judgments, but rather the result of a
 falsehood.

4 *Id.* (citations omitted). Judge Patel went on to hold that the company’s expressions of optimism
 5 based on the study results could not be the basis for a false statement or omission claim, unless
 6 plaintiffs could also allege facts showing that there was no reasonable basis for relying on the
 7 findings of the study, or undisclosed facts tending to seriously undermine the accuracy of
 8 defendants’ opinions. *Id.* at *6 (citing *In re Apple Computer Sec. Litig.*, 886 F.2d 1109, 1113 (9th
 9 Cir. 1989), *cert. denied*, *Schneider v. Apple Computer, Inc.*, 496 U.S. 943 (1990)). Finally, the
 10 Court noted that it was significant that the study “was published in a peer-reviewed journal,
 11 indicating that specialists in the field believed it had some scientific value.” *Padnes*, 1996 WL
 12 539711, at *6. Thus the fact that reasonable minds might differ about the interpretation of the
 13 data could not be the basis for a securities law claim. *Id.*; *DeMarco v. DepoTech Corp.*, 149 F.
 14 Supp. 2d 1212, 1225-26 (S.D. Cal. 2001) (“Although Plaintiffs may have established a legitimate
 15 difference in opinion as to the proper statistical analysis, they have hardly stated a securities fraud
 16 claim.”); *Noble Asset Mgmt. v. Allos Therapeutics, Inc.*, 2005 WL 4161977, at *10-11 (D. Colo.
 17 Oct. 20, 2005) (rejecting plaintiff’s argument that “defendants statements about the interpretation
 18 of data were misleading” and holding that “[i]nterpretations of scientific data are not misleading
 19 where the interpretation finds reasonable support in the data”) (citation omitted).

20 Here, Mr. Bloch states that he would have applied different statistical analyses than
 21 Rigel’s researchers applied. However, three points are critical. First, Plaintiff does not allege that
 22 the “p values” (the widely accepted measure of statistical significance and the focus of Mr.
 23 Bloch’s criticisms) included in Rigel’s December 2007 press release were false. Rather, Plaintiff
 24 simply alleges it would have used a different methodology to measure statistical significance and,
 25 thus, would have presented different p values. Although it is a bit unclear, Mr. Bloch apparently
 26 asserts that rather than using a “chi-square” test, the Company should have used a “Fischer
 27 Exact” test to calculate separate p values for the U.S. and Mexican populations, combined those
 28 results in a single p value using “Fisher’s method,” and then applied a “Tukey’s Studentized

1 Range” test. (¶¶ 76-78, 80.) It is hard to believe a fraud claim can rest on such a theory. Second,
 2 Plaintiff does not allege that the Company falsely claimed it used the methodology proposed by
 3 Mr. Bloch. Rather, Mr. Bloch apparently had no problem identifying the methodology used by
 4 the Company. And third, Plaintiff has failed to allege that the methodology used by Rigel to
 5 measure the results of the study was inconsistent with FDA rules or the protocol agreed to by the
 6 FDA prior to the initiation of the study. In any event, Defendants had no duty to provide
 7 “exhaustive disclosures of procedures used, including alternatives that were not utilized and
 8 various opinions with respect to the effects of these choices on the interpretation of the outcome
 9 data.” *Padnes*, 1996 WL 539711, at *5.

10 In addition, Rigel’s disclosure of cumulative trial results is not rendered misleading by
 11 later disclosure of trial results broken down by country. For instance, Plaintiff takes issue with
 12 the unequal distribution of patients from Mexico and the U.S. in the various placebo and
 13 treatment groups. (¶ 72.) This is precisely the type of “design defect” argument the *Padnes*
 14 Court soundly rejected as insufficient to support a claim for securities fraud. 1996 WL 539711, at
 15 *5. Taken to its logical conclusion, Plaintiff’s argument would mean that a company can neither
 16 combine nor summarize data when disclosing its results, but must disclose at the first instance all
 17 of the raw patient data from its clinical studies. Such a requirement would defeat the purpose of
 18 the securities laws by overwhelming potential investors in an avalanche of immaterial
 19 information. *Twinde v. Threshold Pharms., Inc.*, 2008 WL 2740457, at *9 (N.D. Cal. July 11,
 20 2008) (“An excess of disclosure can have the same net effect as a dearth of it – the shareholder
 21 misses the relevant information.”) (citation omitted).

22 Finally, the Efficacy Claims suffer from an additional, independent flaw that is fatal to the
 23 CAC. Plaintiff does not (and cannot) allege that its loss was “causally connected” to the allegedly
 24 fraudulent p values contained in the 2007 disclosures. The “correct” p values identified by Mr.
 25 Bloch were not disclosed on October 27, 2008 or any other date related to a drop in Rigel’s stock.
 26 Indeed, it appears that they were calculated just recently. Plaintiff’s claim suffers from the same
 27 defect the Supreme Court found in *Dura Pharmaceuticals, Inc. v. Broudo*, 544 U.S. 336, 347
 28

1 (2005): it fails to plead that the Company's stock fell significantly *after the truth became known*.
 2 That is, it has failed to adequately plead the required element of loss causation.

3 The Court should dismiss the Efficacy Claims as a matter of law.

4 **B. The Safety Claims Do Not Allege Any Material Misrepresentation As the
 5 Detailed Data Disclosed in the Scientific Presentations Was Consistent With
 the Earlier Disclosures.**

6 Plaintiff recycles its argument from the previous complaint that Defendants made false
 7 and misleading statements in December 2007 by not reporting every single adverse safety event
 8 at that time. Each of these Safety Claims is based on misleading comparisons between the initial
 9 top-line reporting of the Phase IIa trial results and the far more detailed patient data presented at
 10 the ACR Meeting and in the November 2008 Article. The initial disclosures were true and were
 11 not contradicted by the later, more granular disclosures.

12 Rigel's press release in December 2007 included a table that disclosed patient data related
 13 to "key safety results." (¶ 60.) It is clear from even a cursory reading of this table that Rigel did
 14 not represent that it was disclosing all adverse events (or side effects) that were observed but just
 15 the "key safety results," namely *moderate to severe* adverse events. Regarding neutropenia, the
 16 table clearly included the number of patients whose condition "requir[ed] dose reduction"; with
 17 respect to liver function, the table disclosed the number of patients whose ALT levels were
 18 greater than 3XULN; and with respect to diarrhea, upper GI side effects, and hypertension, the
 19 table disclosed the numbers of patients in each group whose symptoms were considered to be of
 20 "moderate or greater" severity. (*Id.*) No reasonable investor could have reviewed that table and
 21 concluded it included every adverse event observed.

22 Plaintiff claims that Rigel's October 2008 disclosures show that the December 2007
 23 disclosures were fraudulent. But this allegation ignores the fact that the detailed patient data
 24 disclosed in the scientific presentations included *every* adverse event observed in three percent or
 25 more of the patient populations, including *mild* side effects, whereas the initial "top-line"
 26 disclosures described only moderate to severe cases. (See Freeman Decl. Ex. M (Nov. 2008
 27 Article) at 3315, Table 4.) The total numbers of cases in the later disclosures is higher, but only
 28 because those disclosures included patients with mild symptoms.

1 Plaintiff cannot show that the differences in these numbers were material, because the
 2 omission from Rigel's earlier reports of incidents of patients with *mild* symptoms is not a
 3 concealment of risks that would affect the market's perception of R788's potential value.
 4 Further, this Court has recognized that "until adverse incidents are statistically significant, reports
 5 of adverse incidents may be random and may not establish the requisite nexus between the drug
 6 being tested and the adverse events to allege materiality." *Intrabiotics Pharm.*, 2006 WL
 7 2192109, at *12 (withheld adverse reaction reports did not provide statistically significant
 8 evidence that the drugs caused VAP and mortality and thus were not material (citing *Oran v.*
 9 *Stafford*, 226 F.3d 275, 284 (3rd Cir. 2000)); *Borochoff v. GlaxoSmithKline PLC*, 2008 WL
 10 2073421, at *5 (S.D.N.Y. May 9, 2008) (defendant had no duty to disclose meta-analysis of drug
 11 study data which allegedly showed increased risk of heart attack because plaintiffs did not allege
 12 the studies "provided statistically significant evidence that [the drug] caused cardiovascular
 13 risks").

14 As the following discussion demonstrates, Defendants did not make any material
 15 misstatements or omissions with respect to any of the data presented in December 2007:

16 **Liver enzymes:** Plaintiff alleges that in December 2007, Rigel announced a "dose-
 17 dependent increase in alanine aminotransferase ("ALT") in 3 patients in the 150 mg cohort and
 18 none in the 50 mg or 100 mg cohort," but later disclosed that 9 patients experienced increased
 19 liver enzymes. (¶ 106.) This difference, however, is completely explained by the fact that, in
 20 the earlier disclosure, Rigel was referring to patients experiencing ALT levels that were greater
 21 than three times the upper limit of normal ("3XULN") (¶ 109), whereas, in the more
 22 comprehensive scientific disclosures, the reporting threshold was lower – 1.2XULN. (¶ 108).
 23 Rigel clearly discussed this difference. In its December 2007 conference call, Rigel explained
 24 that 3XULN was chosen because it was "the marker that FDA recently recommended in their
 25 guidelines . . ." (¶ 61.)¹⁰

26

27 ¹⁰ Indeed, analysts were not surprised about the more comprehensive disclosures made in 2008
 28 regarding liver enzymes and neutropenia. (See e.g. Freeman Decl. Ex. J, (10/27/08 Credit Suisse)
 at 1 ("We believe the other toxicities, such as the LFT abnormalities and neutropenia were also
 fully disclosed for months and should not have sparked any new concern.").) Analysts did not

1 **Neutropenia:** In its initial disclosures in December 2007, Rigel reported that one of the
 2 most common and clinically meaningful adverse effects observed during the trial was neutropenia
 3 and that a total of 15 patients – 5 patients in the 100 mg dose group and 10 patients in the 150 mg
 4 dose group – required a dose reduction because of low neutrophil counts. (¶ 60; *see also* Freeman
 5 Decl. Ex. D (12/13/07 8-K/PR) at 2.) The exact same disclosure was made in the November 2008
 6 Article: “Ten percent of the patients in the R788 100 mg group and 21% of the patients in the 150
 7 mg group had an adjustment in the study dose, as mandated by the study protocol, when the
 8 absolute neutrophil count dropped to <1500 cells/mm³.” (Freeman Decl. Ex. M (Nov. 2008
 9 Article) at 3315.) Simple math demonstrates that these figures are exactly the same as what was
 10 disclosed previously.¹¹ Plaintiff’s only criticism here is that the November 2008 Article reflects
 11 that an additional five patients had some level of neutropenia that did *not* require a dose
 12 reduction. (¶ 110.)

13 **Diarrhea and Upper GI Side Effects:** Plaintiff claims that Defendants disclosed only 15
 14 cases of diarrhea and 15 cases of upper GI side effects in December 2007, but later disclosed 34
 15 cases of diarrhea and 35 cases of upper GI side effects in October 2008. (¶¶ 112-113). Again, an
 16 accurate reading of the Company’s disclosures demonstrates that these differences are innocuous:
 17 the earlier disclosures reported cases of those side effects that were “severity moderate or
 18 greater,” while the later scientific presentations, included *all* reported cases of diarrhea and upper
 19 GI side effects, regardless of severity. (*See* Freeman Decl. Ex. D (12/13/07 8-K/PR) at 2, Ex. M
 20 (Nov. 2008 Article) at 3315.)

21 **Hypertension and Blood Pressure:** In December 2007, Rigel disclosed that two of the
 22 patients in the Phase IIa study who were on R788 had experienced moderate to severe
 23 hypertension. (Freeman Decl. Ex. D. (12/13/07 Form 8-K/PR) at 2.) Plaintiff does not allege

24 even comment on the more detailed data announced in 2008 related to diarrhea and upper GI
 25 effects. (*See e.g.* Freeman Decl. Ex. J (10/27/08 Credit Suisse); Ex. K (10/28/08 Jeffries & Co.);
 26 Ex. L (10/28/08 Oppenheimer).)

27 ¹¹ Table 4 of the November 2008 Article shows that there were 49 patients in the 100 mg group
 28 and 47 patients in the 150 mg group. (Freeman Decl. Ex. M (Nov. 2008 Article) at 3315.) Five
 of the 49 patients in the 100 mg group equals ten percent; and ten of the 47 patients in the 150 mg
 group equals 21 percent.

1 that that statement was false, or that more than two patients experienced hypertension of moderate
 2 or greater severity. The undisputed truth is that there were only two. Instead, Plaintiff argues that
 3 the statement was misleading because three other patients experienced hypertension of a severity
 4 less than moderate, one patient had an increase in blood pressure as high as 30 mmHg, and there
 5 was a small dose-dependent increase in average blood pressure. Plaintiff fails to provide a
 6 plausible rationale for why any of this additional information would have been material in light of
 7 the disclosures that were made.¹²

8 First, Plaintiff fails to demonstrate how the omission of incidents of *mild* hypertension is a
 9 concealment of risks that would materially affect the market's perception of R788's potential
 10 value. A reasonable investor confronted with the December 2007 press release containing data
 11 regarding cases of moderate or more severe hypertension would understand that the summary
 12 data did not include less pronounced hypertension. Dr. Grossbard's statements during the
 13 conference call confirmed that understanding:

14 The incidence of reported *moderate* hypertension was quite low,
 15 although the way case report forms are filled out an occasional
 16 patients [sic] had a notation for his systolic blood pressure increase,
 17 and an occasional one had diastolic pressure increase. And it is
 hard to know exactly what that means, so I'm reporting to you here
 those where the case report forms noted, hypertension of *moderate*
 severity.

18 (Freeman Decl. Ex. E (12/13/07 trans.) at 3 (emphasis added).) In fact, the market appreciated
 19 such a possibility in December 2007. (*See, e.g., id.* Ex. F (12/13/07 CIBC World Markets, CAC
 ¶¶ 50, 79, 82, 83) at 4 ("Rigel did not report the rates of mild hypertension in this study.
 21 However, even if mild hypertension were to be observed, we believe this would likely be
 22 acceptable in the moderate-to-severe RA setting . . .").)

23
 24
 25 ¹² Plaintiff also alleges that during the conference call regarding the results of an earlier R788
 26 study, Dr. Grossbard "flagged that a mean increase in systolic blood pressure of 5 mm Hg *might*
 27 *present a problem if observed.*" (¶ 59 (emphasis added).) This is just not true. Dr. Grossbard
 28 actually stated, "In the rheumatoid arthritis study, while I don't know we are still blinded, the
 overall incidence of that is quite low, so I don't think it's a very, very prevalent problem, although
 I can't say that at a higher dose, the mean population increase in systolic pressure won't be 5
 millimeters or what, I just don't know that yet." (Freeman Decl. Ex. C (12/04/07 trans.) at 6.)

1 As for the fact that the largest increase in blood pressure observed was as high as 30 mm
 2 Hg, Plaintiff fails to explain why this additional detail would be material. Rigel disclosed in
 3 December 2007 that two patients experienced moderate to severe hypertension. If the patient
 4 who saw an increase in his or her blood pressure of 30 mm Hg was one of those two patients, then
 5 it is unclear why detail about the increase would add anything meaningful to the initial
 6 disclosures. If the patient was not one of the two experiencing moderate or severe hypertension,
 7 then it is unclear why a potentially transitory increase in blood pressure that did not result in
 8 hypertension would be material to investors. Further, as Dr. Grossbard made clear, a single
 9 reading of a 20-30 mm Hg increase in blood pressure has little clinical meaning. (*Id.* Ex. I
 10 (10/27/08 trans.) at 4.) Because of this, physician guidelines issued by the United States
 11 government recommend that a doctor wait one or two months to monitor blood pressure readings
 12 before determining whether to use anti-hypertensive drugs to treat Stage 1 or Stage 2
 13 hypertension. (*See* Freeman Decl., Ex. A (U.S. Department of Health and Human Services,
 14 Agency for Healthcare Research and Quality “Hypertension Guidelines” (last verified Nov. 28,
 15 2006) at 7.) This is because an individual’s blood pressure can vary greatly, and physicians do
 16 not place much value on a single reading.¹³

17 Finally, Plaintiff argues that Rigel should have disclosed in December 2007 that there was
 18 a dose-dependent average increase in blood pressure. The argument fails on several fronts. First,
 19 Plaintiff completely fails to allege that such small increases in average blood pressure are
 20 clinically significant in any way. Second, the Company disclosed that there were a small number
 21 of patients that experienced moderate to severe hypertension, a medical condition that often
 22 requires treatment. That is, the 2007 disclosures clearly indicated that there was a blood pressure
 23 risk with the drug. In light of that fact, it is unclear what information regarding a small increase
 24 in average blood pressure levels would add. Third, it is unclear why Plaintiff claims the *average*

25
 26 ¹³ Analysts agreed with Dr. Grossbard’s assessment that an isolated increase in blood pressure has
 27 no meaning. (*Compare* Freeman Decl. Ex. I (10/27/08 trans.) at 4 and Ex. N (11/3/08 trans.) at
 28 10 with Ex. K (10/28/08 Jefferies, CAC ¶ 129) at 1 (“Our physician consultants do not see these
 BP increases as clinically meaningful or an important impediment to R788 approval – and we
 concur.”).)

1 increase in blood pressure was material information that needed to be disclosed when it fails to
 2 make a similar claim regarding the *average* increase in liver enzymes or the *average* decrease in
 3 neutrophils. And finally, at least one analyst understood, based on the information previously
 4 disclosed by the Company in 2007, that a dose-dependent increase in blood pressure should not
 5 have been a surprise in 2008. (See, e.g., *id.* at Ex. J (10/27/08 Credit Suisse, CAC ¶¶ 60, 66, 129)
 6 at 1 (“In terms of toxicity, R788 had a dose dependent increase in blood pressure (BP), which
 7 should not have been a surprise as the company has talked about the effect on BP since the data
 8 were first presented.”).)¹⁴

9 **VI. THE SECTION 10(B) CLAIMS SHOULD BE DISMISSED BECAUSE PLAINTIFF HAS NOT
 10 ALLEGED SPECIFIC FACTS GIVING RISE TO STRONG INFERENCE OF SCIENTER.**

11 **A. Lack of insider sales is powerful evidence of lack of scienter.**

12 Plaintiff fails to allege that any defendant sold a single share of stock during the Class
 13 Period, undercutting any strong inference of scienter. Courts have repeatedly held that “the
 14 absence of insider trading by a defendant is highly relevant and undermines any inference of
 15 scienter.” *In re Pixar Sec. Litig.*, 450 F. Supp. 2d 1096, 1107 (N.D. Cal. 2006); *see also Metzler
 16 Inv. GMBH v. Corinthian Colleges, Inc.*, 540 F.3d 1049, 1067 (9th Cir. 2008) (stating that where
 17 one individual “sold nothing at all” it suggests “that there was no insider information from which
 18 to benefit”). In *In re Tibco Software Securities Litigation*, 2006 WL 1469654, at *20-21 (N.D.
 19 Cal. May 25, 2006), the Court held that plaintiff’s stock sale allegations were insufficient, and
 20 found dispositive the fact that several of the defendants did not sell any shares of stock. *Id.* at
 21 *20; *In re Ashworth, Inc. Sec. Litig.*, 2000 WL 33176041, at *11 (S.D. Cal. July 18, 2000).

22 In this case, none of the Company’s officers (or directors) named in the Complaint sold
 23 any Rigel stock during the Class Period. (See Freeman Decl. ¶¶ 18-19, Ex. Q and Ex. R (Form

24
 25 ¹⁴ Other analyst reports confirm that investors understood R788’s effect on blood pressure and
 26 were not misled in any way. Plaintiff selectively quotes Credit Suisse analyst Aberman’s report,
 27 that such a raise in blood pressure “could precipitate significant morbidity acutely,” but ignores
 28 the remainder of Aberman’s report, which repeatedly states that there was nothing surprising
 about the October 2008 disclosures and that “new data [did] not dramatically change our view.”
 (Freeman Decl. Ex. J (10/27/08 Credit Suisse, CAC ¶¶ 60, 66, 129) at 1) (“[T]he company has
 talked about the effect on [blood pressure] since the data were first presented.”).)

1 4s.) Rather, the exposure of each of these individuals to the Company's stock increased during
 2 the class period as their stock options became exercisable. (See *id.* ¶ 20 and Ex. B (March 26,
 3 2007 Form DEF14A) at 45; Freeman Decl. Ex. H (April 8, 2008 Form DEF14A) at 39; Ex. P
 4 (April 15, 2009 Form DEF14A) at 23.) These undisputed facts are inconsistent with an intent to
 5 profit from fraud. See *In re PetSmart, Inc. Sec. Litig.*, 61 F. Supp. 2d 982, 1000 (D. Ariz. 1999)
 6 ("[W]e find that defendant . . . did not sell any shares of stock . . . and there can be no argument
 7 therefore that she was motivated to defraud PetSmart investors by a desire to maximize personal
 8 economic benefit."). Without any stock sales to support an inference of scienter, Plaintiff instead
 9 argues that the Defendants owned stock options and stood to gain from the stock's artificially
 10 inflated price. (¶¶ 142, 145-147.) But not only did no Defendant sell stock during the alleged
 11 class period; Messrs. Gower and Payan actually did the opposite – they exercised options in
 12 January 2009 and *held* those shares. (See Freeman Decl. ¶ 18 and Ex. Q and Ex. R (Form 4s).)

13 **B. Compensation, the need for capital and the importance of R788's success to
 14 Rigel do not give rise to a strong inference of scienter.**

15 Plaintiff's other generic scienter allegations are no more compelling. For example,
 16 Plaintiff speculates that Defendants acted in order to increase their compensation and to avoid
 17 bankruptcy, but courts routinely reject allegations of motive based on executive compensation.
 18 See, e.g., *Constr. Laborers Pension Trust v. Neurocrine Biosciences, Inc.*, 2008 WL 2053733, at
 19 *7 (S.D. Cal. May 13, 2008); *In re Cornerstone Propane Partners, L.P. Sec. Litig.*, 355 F. Supp.
 20 2d 1069, 1091 (N.D. Cal. 2005). Courts also reject scienter claims based on a company's desire
 21 to raise capital. See *Lipton v. Pathogenesis Corp.*, 284 F.3d 1027, 1038 (9th Cir. 2002)
 22 (company's "alleged desires to obtain favorable financing" were "ordinary and appropriate
 23 corporate objectives" and did not create an inference of scienter).

24 **C. The more compelling inference from Plaintiff's allegations, taken as a whole, is
 25 that Defendants lacked scienter.**

26 Plaintiff fails to identify a single confidential witness or document supporting its scienter
 27 allegations. Moreover, it simply ignores several other facts that are relevant to determining what
 28 inference is the most cogent and compelling: (1) Although Rigel did not disclose all the details

1 Plaintiff claims it should have in 2007, the Company did disclose the most serious side effects
 2 that patients in the study experienced. (2) The Company voluntarily disclosed the additional
 3 detail – the detail that Plaintiff alleges it tried so hard to conceal in 2007 – at a medical
 4 conference and in a medical journal in the fall of 2008. There is no allegation that the Company
 5 was under any sort of compulsion to do so. (3) During the period in which the price of Rigel’s
 6 stock was allegedly inflated due to the fraudulent conduct of Defendants, none of the Defendants
 7 sold any of their stock in the Company. (4) During that same period, each of the five officer
 8 Defendants actually increased the number of shares (and options) they owned. (¶ 145.) And (5)
 9 by holding on to their stock in the weeks leading up to the 2008 ACR conference when they
 10 allegedly knew that “the truth would come out,” those five Defendants together lost in excess of
 11 \$18.7 million.¹⁵

12 The far more compelling inference to be drawn from all these facts and allegations is that
 13 Defendants acted in good faith without the intent to deceive. Had Defendants actually been
 14 acting with scienter, one would expect that they would have sold stock before making more
 15 detailed disclosures at a scientific conference, or avoided the more detailed disclosures and
 16 proceeded to a Phase III trial. Defendants suffered a far larger financial loss by holding onto their
 17 existing shares and increasing their financial exposure to the Company than they did by securing
 18 the raises and bonuses identified by Plaintiff. As a result, the first and second claims for relief
 19 should be dismissed.

20 **VII. PLAINTIFF’S SECTION 20(A) AND SECTION 15 CLAIMS SHOULD BE DISMISSED FOR**
 21 **FAILURE TO ALLEGE A PRIMARY VIOLATION OR THE REQUISITE “CONTROL.”**

22 Because Plaintiff has failed to state a claim under Sections 10(b), 11, or 12(a)(2),
 23 Plaintiff’s control person claims under Sections 20(a) and 15 must be dismissed. *See Lipton*, 284
 24 F.3d at 1035 n.15; *In re Harmonic, Inc. Sec. Litig.*, 163 F. Supp. 2d 1079, 1090 (N.D. Cal. 2001).
 25 Even if Plaintiff had alleged a primary violation of the securities laws, the “control person”

26 ¹⁵ According to the CAC, the price of Rigel stock fell \$5.57 on October 27, 2008, and \$.67 on
 27 February 3, 2009, as a result of the alleged fraud being disclosed. (¶¶ 18, 20.) According to SEC
 28 filings, the five officer Defendants owned roughly 3 million shares outright or through options
 during that time period. (See Freeman Decl. ¶ 20.)

1 claims should be dismissed as Plaintiff has not pled with specificity facts showing each
 2 Defendant's ability to exercise control over the activity on which the primary violation is
 3 premised. *Lilley v. Charren*, 936 F. Supp. 708, 716 (N.D. Cal. 1996).

4 **VIII. CONCLUSION.**

5 For the foregoing reasons, Defendants respectfully request that the Court grant
 6 Defendants' motion to dismiss Plaintiff's Consolidated Amended Complaint with prejudice.

7

8 Dated: February 16, 2010

COOLEY GODWARD KRONISH LLP

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 11 /s/
 William S. Freeman

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14 Attorneys for Defendants RIGEL
 15 PHARMACEUTICALS, INC., and the
 16 INDIVIDUAL DEFENDANTS

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